

U.S.S.N. 09/625,963

Filed: July 26, 2000

RESPONSE TO OFFICE ACTION**Remarks****Rejection Under 35 U.S.C. § 102**

Claims 1, 5, 7, 15, and 19 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Application Publication No. 20030082196 by Gaiger, et al. ("Gaiger"), which claims priority to U.S. Patent Application No. 09/164,223, ("the '223 application") filed September 30, 1998. Applicants respectfully traverse this rejection.

The claims are limited to HLA-A0201-positive antigen presenting cells (APC) and treatment of HLA-A0201-positive tumor cells, which aberrantly express WT-1. Gaiger does not disclose or suggest these limitations. Accordingly, applicants feel that the claims are not anticipated by Gaiger. However, to facilitate prosecution of the present application, applicants submit a Declaration Under 37 C.F.R. § 1.131 by Hans Josef Stauss and Liquan Gao. In their declaration, Hans Josef Stauss and Liquan Gao state that prior to September 30, 1998 they conceived and reduced to practice the peptide containing the amino acid sequence RMFPNAPYL, as defined by the claims of the present application.

As noted in the copies of the laboratory notebook pages attached to the Declaration (Exhibit A), peptides containing the amino acid sequence RMFPNAPYL, represented as WT126 or pWT126 in Exhibit A, bound to HLA-A0201, represented as HLA-A2 in Exhibit A, on T2 cells (see page 3). This demonstrates that applicants were in possession of peptides containing the amino acid sequence RMFPNAPYL and that the peptide binds to HLA-A0201-positive antigen presenting cells (APC). As noted in Exhibit A, pages 4-5, cytotoxic T-cells (CTL) kill T2 target cells incubated with WT126 peptide. This demonstrates that the peptide is capable of

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3

ICI 101
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U.S.S.N. 09/625,963

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eliciting a CTL response. As noted in Exhibit A, pages 6-7, cytotoxic T-cells (CTL) incubated with WT126 peptide kill target cells endogenously expressing WT-1. This demonstrates that the peptide is capable of eliciting a CTL response against cells expressing the WT-1 protein. As noted in Exhibit A, pages 8-9, cytotoxic T-cells (CTL) incubated with WT126 kill CD34+ chronic myelogenous leukemia (CML) cells. The specification at least at page 8, lines 26-27, disclose that leukemias over-express WT-1. This demonstrates that the peptide is capable of eliciting a CTL response against tumor cells expressing HLA-A0201 and over-expressing WT-1.

Gaiger discloses peptides containing the amino acid sequence RMFPNAPYL at least at page 1, paragraph 0008 and at page 6, paragraph 0053. As noted above, applicants had conceived of and reduced to practice peptides containing the amino acid sequence RMFPNAPYL prior to September 30, 1998. Therefore, Gaiger is not available as prior art under 35 U.S.C. § 102(e).


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Allowance of claims 1, 5, 7, 15, and 19 is respectfully solicited.

Respectfully submitted,



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